Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID P.L. SACHS

Appeal No. 2001-0870
Application No. 08/422,381

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 37-46, all of the claims remaining. Claim 37 is representative and reads as follows:

> 37. A method for determining a nicotine dosage necessary to achieve a target nicotine serum concentration in an individual patient who is ceasing smoking, said method comprising:
>
> (A) measuring a patient nicotine concentration while the patient is still smoking; and
>
> (B) determining the nicotine dosage as follows:
>
> (i) for male patients:

> determining the values of at least a body mass factor and a cumulative smoking factor; and
>
> determining the dosage to achieve the target nicotine serum concentration based on the patient's measured nicotine concentration, the body mass factor value, and the cumulative smoking factor value; or
>
> (ii) for female patients:
>
> determining at least the value of a psychological dependence factor and age; and
>
> determining the dosage to achieve the target nicotine serum concentration based on the patient's measured nicotine concentration, the psychological dependence factor value and the age.

The examiner relies on the following references:

Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 6th Ed., pp. 43-48 (1980)

DiPiro et al. (DiPiro), "Chapter 2/ Drug Delivery and Administration," Pharmacotherapy : A Pathophysiologic Approach, pp. 15-17 (1989)

Chan et al. (Chan), "Pharamacokinetics of a single transdermal dose of nicotine in healthy smokers," Journal of Controlled Release, Vol. 14, pp. 145-151 (1990)

Claims 37-46 stand rejected under 35 U.S.C. § 103 as obvious in view of the combined disclosures of Chan, DiPiro, and Goodman & Gilman.

We reverse.

Background

"[A] number of products have been commercially developed for providing nicotine replacement while a patient is undergoing smoking cessation . . ., including gums, transdermal patches, nasal spray, inhalers, lozenges, and the like." Specification, page 1. The specification discloses that the dosage of

nicotine delivered during nicotine therapy affects the long-term success of the therapy. "[L]ong term patient abstinence is achieved more often in those patients where at least 40%, usually at least 50%, of pre-cessation blood nicotine levels . . . are maintained by the replacement therapy." Page 3.

The specification discloses methods for determining the optimal dosage for nicotine replacement therapy for a particular patient. The disclosed method takes into account several factors, including "a body mass factor, a cumulative smoking factor, a psychological dependence factor, age, and menopausal status." Page 3. However, not all of these factors are important for every patient.

> The preferred patient characteristics will vary between males and females. For males, the preferred patient characteristics include at least the body mass factor and the cumulative smoking factor. The psychological dependence factor and patient age are also useful, although not as predictive as the body mass factor and the cumulative smoking factor. For females, the preferred patient characteristics include at least the psychological dependence factor and age. Menopausal status is also a significant factor, although less so than the previously mentioned factors. The cumulative smoking factor appears to be of little relevance to predicting the relationship between dosage and blood nicotine levels in women.

The specification provides further details on the meaning of, e.g., "body mass factor," "cumulative smoking factor," and "psychological dependence factor" on pages 6-7.

Discussion

The claims are directed to a method for determining a nicotine dosage based on at least, for males, the patient's body mass factor and cumulative smoking factor or, for females, the patent's psychological dependence factor and

age. The examiner rejected all of the claims as obvious in view of Chan, DiPiro, and Goodman & Gilman.

The examiner characterizes Chan as "teach[ing] that nicotine replacement therapy is well known as an aid in smoking cessation therapy." Examiner's Answer, page 4. The examiner concedes that Chan does not teach "methods for determining or optimizing nicotine replacement dosages based on values corresponding to various patient characteristics," id. at page 5, but relies on DiPiro and Goodman & Gilman to make up this deficiency.

> The secondary references teach the individualization of drug therapy, broadly, based on factors similar to those therein [sic], is conventional in the pharmaceutical art. See, e.g., in DiPiro et al. page 16, Table 2.1 and Goodman [&] Gilman et al. page 43, Figure 3.1. One of ordinary skill would therefore have ample motivation to determine nicotine replacement dosages in therapy by employing such factors. Further, the optimization of amounts of agents to be employed is deemed to be within the skill of the artisan.

Examiner's Answer, page 5

Appellant argues that the examiner's references do not teach or suggest all of the claim limitations. See the Appeal Brief, page 10:

> [N]o reference or combination thereof teaches or suggests that a nicotine replacement dosage can be individualized and based on particular characteristics specific to an individual patient. Furthermore, no reference or combination thereof remotely implies that nicotine dosage determinations for male and female patients depend on entirely different sets of primary factors, as set forth in claim 37.

Appellant also argues that, in addition to not teaching the limitations of the claims, the cited reference do not provide adequate motivation to combine what

they do teach, nor do they provide a reasonable expectation of success. Appeal Brief, pages 12-14.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

In this case, we agree with Appellant that the examiner has not established a prima facie case of obviousness. The references cited by the examiner disclose that nicotine patches were known in the art (Chan), and that the effective dose of a therapeutic drug would depend on a number of factors, including "disease state," "sex," and "age" (DiPiro, page 16), as well as "body size and composition" and "physiological variables" generally (Goodman & Gilman, page 43). However, none of the references discuss factors to consider in optimizing the dosage of nicotine specifically. In fact, none of the references even recognize a need to optimize nicotine dosages, let alone suggest using the factors recited in the claims to do so. The claimed method requires considering specific factors, which vary depending on the sex of the patient, in order to calculate an individualized dosage. The examiner has pointed to nothing in the references that would have led those of skill in the art to consider specifically the

factors recited in the claims, and in particular, to have considered different factors depending on whether the patient was male or female.

"The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (citations omitted). In this case, the references cited by the examiner may have made it obvious to try varying different factors to see if they affected the dosage effectively delivered by a nicotine patch, but they would not have rendered obvious the claimed method.

Summary

We reverse the rejection under 35 U.S.C. § 103 because the references cited by the examiner do not support a prima facie case of obviousness.

REVERSED

Toni R. Scheiner Administrative Patent Judge	)
Eric Grimes Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
8th Floor
SAN FRANCISCO , CA 94111-3834

EG/jlb